FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee (AVDAC)
Hilton Hotel, Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, MD
June 2, 2010

Questions to the Advisory Committee

The committee will discuss biologics license application (BLA) 125283, motavizumab, single-dose liquid solution 50 mg/0.5 milliliter (mL) and 100 mg/1 mL vials, MedImmune, LLC, for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.

1) Please comment on the safety profile of motavizumab, specifically with respect to the potential for hypersensitivity reactions including life-threatening anaphylaxis.

2) Do the data from the applicant's studies adequately support the efficacy of motavizumab for the prevention of serious lower respiratory tract infection with RSV in at risk infants?

3) Given the potential benefits and risks, should motavizumab be licensed for marketing?

   Vote: Yes/No/Abstain

   Please discuss the rationale for your vote.

   1. If no, what additional data/studies can be provided to support the licensing of motavizumab?

   2. If yes, are there post-marketing studies needed to provide data that would aid in safer or more optimal use of motavizumab?